

**REMARKS**

The Office Action mailed May 17, 2006 has been carefully considered by applicant. Reconsideration is respectfully requested in view of the foregoing claim Amendment in the remarks that follow.

**Claim Objections**

Claims 3, 5, 6, 13, 15, 16, 23, 25, 26, 29, 30 and 31 have been objected to because of a lack of antecedent basis. By the present Amendment, the claims are amended to provide proper antecedent basis for the aforementioned claims. As such, the claim objections are believed obviated.

**Claim Rejections Under 35 USC § 101**

Claims 2-3, 5-9, 12-19, 22-23, 25-26 and 28-32 have been rejected under 35 USC §101 as being directed to non-statutory subject matter. By the present Amendment, the aforementioned claims have been amended per the Examiner's suggestion and no longer positively recite the human body. As such, the claim rejections are believed obviated.

**Claim Rejections Under 35 USC §112**

Claims 4 and 24 have been rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. By the present Amendment, claims 4 and 24 are amended to more clearly refer to the first, second, third and fourth electrodes. As such, the claim rejections under §112, second paragraph are being obviated.

**Claim Rejections Under 35 USC §102 & §103**

Claims 1-6, 10 and 21-26 have been rejected 35 USC §102(b) as being anticipated by Lisiecki, U.S. Patent No. 6,083,156. Claims 7-9 have been rejected under 35 USC §103 based on Lisiecki '156 in view of alleged admitted prior art. Claims 11-32 have been

rejected under 35 USC §102(b) as anticipated by Lisiecki '156, or in the alternative under 35 USC §103(a) as being obvious over Lisiecki '156 in view of Duckert, U.S. Patent No. 6,389,312.

By the present Amendment, claims 1-32 are amended to more clearly set forth the subject matter of the present invention and to render the same allowable over the applied references. The independent claims (claims 1, 11, 21 and 27) are amended to recite a base element that is adapted for attachment to the head of a patient. An example of such an arrangement is shown in the figures (element 9) and discussed throughout the application, including paragraph 19, wherein it is stated that the base element 9 can be made of an appropriate flexible material, such as for example plastic material. In combination with the base element, the independent claims recite at least one connector attached to the base element and adapted to connect the sensor arrangement to a patient monitor. An example of the claimed at least one connector is shown in the figures (element 10) and is discussed throughout the application, including at paragraph 9. An array of electrodes are connected to the at least one connector and the connector attaches the electrodes to a patient monitor.

Lisiecki '156 fails to teach or suggest the claimed "base element adapted for attachment to the head of a patient". Instead, Lisiecki '156 describes a device having discrete sensors and lead wires, "a plethora of sensors and auxiliary devices" connected to a monitoring system. In paragraph 7 of the Office Action, the Examiner compares the claimed base element to the chassis of electronic components (electronics unit 100) of Lisiecki '156. However, clearly, the electronics unit 100 is not adapted for attachment to the head of a patient, per the amended independent claims of the present application. Therefore, the amended independent claims (claims 1, 11, 21 and 27) are clearly not anticipated by the Lisiecki '156 reference.

For further understanding, the Examiner is referred to paragraph 7 of the application wherein it is noted that a considerable problem in operating rooms is the large number of cables and hoses extending from the patient to a patient monitor and other devices connected to the patient. Traditionally, separate sensors have been connected for example to a patient monitor using a cable of its own or a hose of its own. One reason the present invention is unique is because it provides a compact multi-parameter sensor in which all sensors are connected to a single structure attached to the patient, i.e. the base element that is adapted for attachment to the head of a patient. In contrast, Lisiecki '156 exemplifies a prior art system that has the problems noted in paragraph 7 of the application. For example, complicated arrangements of cables and hoses having multiple connections are easily tangled and can result in delays and mistakes in the operating room. This clear difference between the claimed invention and the cited art is further evidence that the art does not anticipate or render obvious the invention of the independent claims (claims 1, 11, 21, and 27).

Many of the dependent claims of the present application are further amended to define the type and positioning of specific electrodes within the claimed array of electrodes. For example, as stated at paragraph 9, one embodiment of the invention is unique because the user only has to attach one sensor instead of three separate sensors, Entropy, NMT and SpO<sub>2</sub>. In addition, all these parameters are measured from the same area, i.e. the head of the patient. There is no need to attach sensors on the hands of the patient, which would typically be the case for NMT and SpO<sub>2</sub>. Instead, the user only needs to connect one cable to the sensor since all parameters are connected through the claimed connector, which is attached to the base element and arranged on the head of the patient.

The Examiner states in the Office Action paragraphs 7-17 that the recitation of "intended use" has been discounted, and even so, it is "possible" or merely "design choice" to arrange the disposable electrode tabs and corresponding alligator clips of Lisiecki '156 in

the same manner as that claimed. However, applicant strongly traverses these opinions. Only according to the presently claimed arrangement is there provided a base element for attachment to the head of a patient and a connector attached to the base element and adapted to connect the sensor arrangement to a patient monitor, wherein an array of electrodes is connected to the at least one connector. Therefore, only according to the present invention are the advantages discussed in paragraph 9 provided, and only according to the present application are the specific types and arrangements of sensors recited in the claims provided. Applicant respectfully calls upon the Examiner to cite a reference in support of his opinions regarding "design choice". Applicant also strongly asserts that the type of sensor (e.g. EEG, EMG, etc.) is not an "intended use" but rather a structural limitation, and therefore should be interpreted as such.

In paragraph 8 of the Office Action, the Examiner states that the specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, however it is possible to arrange the same in the manner described in claim 2. Applicant respectfully disagrees with the Examiner's conclusion and requests that he cite a reference in support of his opinion. Applicant notes that claim 2 must be considered in combination with the elements of claim 1. Clearly the art does not teach or suggest first and second electrodes in the array of electrodes adapted for location just posterior to the lower part of the pinna and just anterior to the tragus to stimulate the facial nerve when the base element is attached to the head of the patient.

Regarding paragraph 9, applicant respectfully requests that the Examiner cite a reference in support of his opinion that it is possible to arrange the electrode tabs and corresponding alligator clips according to the arrangement of claim 3. Applicant also notes that claim 3 must be considered in combination with claim 1, which recites the array of electrodes and optical sensor adapted to monitor substances in tissues and connected to the at least one connector.

Regarding paragraph 10, applicant has amended claim 4 to recite that the first, second, third and fourth electrodes are adapted to measure NMT response. Applicant asserts that this is not an "intended use" and therefore provides a structural limitation, which is not found in the art in combination with the other claimed structure.

Regarding paragraph 11, applicant respectfully requests that the Examiner cite a reference in support of his position that "it is possible" to position the combination of disposable electrode tabs and miniature alligator clips in the configuration described in this claim. The Examiner is reminded that claim 6 must be considered in combination with claims 1 and 5. The art does not show an additional electrode that is adapted for location on the temple area between the corner of the eye of the patient when the claimed base element is attached to the head of the patient. As discussed above, the art fails even to teach or suggest a base element that is attached to the head of the patient, much less the specific arrangement recited in claim 6.

Regarding paragraph 14, the Examiner states that specific placement of the disposable electrode tabs and corresponding alligator clips are not taught, although it is possible to arrange the same in the manner described in claim 22. Applicant respectfully disagrees with this statement. The Examiner is reminded that claim 22 must be considered in combination with claim 21, which recited the base element adapted for attachment to the head of a patient. Certainly, the art does not teach or suggest a first and second electrode in the array of electrodes that are NMT stimulus electrodes adapted for location just posterior to the lower part of the pinna and just anterior to the tragus to stimulate the facial nerve when the claimed base element is attached to the head of the patient.

Regarding paragraph 15, the Examiner states that claims 23 and 25 recite intended use of the structure. Claims 23 and 25 are amended to state that the array of electrodes are adapted to measure EEG and EMG. Applicant asserts that this is not an intended use

limitation, but rather a structural limitation. As such, the Examiner is respectfully requested to cite a reference in support of any rejection of these claims

Regarding paragraph 16, the Examiner states that claim 24 merely recites intended use. By the present Amendment, claim 24 is amended to state that the first, second, third and fourth electrodes are adapted to measure NMT response. Claim 24 does not recite intended use, but rather is a structural definition. The Examiner is requested to cite a reference in support of his opinion of intended use.

Regarding paragraph 17, the Examiner states that claim 26 recites intended use. Claim 26 is hereby amended to recite that the second electrode and the third electrode of the three electrodes are able to measure NMT response. Applicant asserts that this is not a recitation of intended use, but rather a structural limitation. The Examiner is requested to cite a reference in support of his opinion regarding this claim.

Regarding paragraph 19 of the Office Action, the Examiner states that the limitation "an optical sensor that is capable of being attached to the forehead, to the root of the nose, or to the ear" is rejected in view of Lisiecki '156 in view of admitted prior art. Claims 7, 8 and 9 are amended by the present Amendment to state that the respective optical sensor for monitoring substances in tissues is adapted for location on the forehead of the patient when the base element is attached to the head of the patient. The Examiner states that it would have been a matter of "design choice" to make the pulse oximeter taught by Lisiecki to be capable of being attached to the forehead, to the root of the nose, or to the ear, as choosing any of these embodiments would be equivalent over another similar optical device that is capable of being placed on a finger, toe, earlobe or any other body part. Applicant respectfully but strongly disagrees with the Examiner's conclusion because the subject matter of claims 7-9 must be considered in combination with the subject matter of claim 1. Applicant strongly asserts that the arrangement of claim 1, *in combination with* the recited

optical sensor that is adapted for location on the forehead of the patient when the base element is attached to the head of the patient is neither taught nor suggested, nor rendered obvious by the cited references, nor the alleged admitted prior art. The fact that the prior art fails to teach or suggest a base element that is attached to the head of a patient by itself overcomes the rejection set forth in paragraph 19 of the Office Action.

In paragraph 21 of the Office Action, the Examiner states that it would have been possible to locate a sensor in the locations described in claims 11, 14 and 16 and therefore these elements do not form a basis for a limitation of this claim. Applicant respectfully traverses the Examiner's conclusion, per the discussion above regarding the unique type and arrangement of sensors in the present invention.

Regarding paragraphs 22-28, the Examiner makes assertions regarding the "possibility" of arranging the claimed sensors in the manner described in the rejected claims. Based upon the arguments provided above, applicant respectfully traverses this opinion. In addition, the claims are amended to more particularly point out and specifically claim the subject matter of the present invention and render the same allowable over the applied references. The specific arrangement and type of sensors in combination with the structure recited in the independent claims is unique, novel and not obvious in view of the prior art references. The Examiner's assertion of "design choice" and "intended use" are respectfully traversed, in accordance with the reasoning provided above.

The Examiner cites Duckert '312 as teaching a mechanical NMT sensor. Clearly, NMT sensors are well known in the art, however Duckert '312 fails altogether to teach or suggest the claimed base element for attachment to the head of a patient, and also fails to teach the at least one connector attached to the base element and adapted to connect the sensor arrangement to a patient monitor. As such, for the reasons stated above, the claims are not rendered obvious by a combination of Lisiecki '156 and Duckert '312.

Application No. 10/688,863  
Amendment Dated October 12, 2006  
Reply to Office Action of May 17, 2006

**Conclusion**

The present application is thus believed in condition for allowance with claims 1-32.  
Such action is respectfully requested.

Respectfully submitted,

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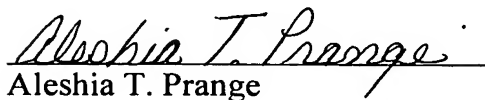


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Aleshia T. Prange

10-12-2006  
Date